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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,973	08/02/2006	Jairam R Lingappa	UCSF.011.00US	7515
58280	7590	02/12/2009	EXAMINER	
JONATHAN ALAN QUINE THE QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. 2033 CLEMENT AVE. #200 ALAMEDA, CA 94501			KINSEY WHITE, NICOLE ERIN	
		ART UNIT	PAPER NUMBER	
		1648		
		MAIL DATE	DELIVERY MODE	
		02/12/2009	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/527,973	LINGAPPA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03 November 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 1-24 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 25 and 26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

The amendment filed on January 30, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants updated the first line of the specification (continuity data) via a Preliminary Amendment filed on January 25, 2007. This amendment stated "This application is a 371 of PCT/US2004/028622, filed September 11, 2003, which claims benefit of U.S. Provisional Application Serial No. 60/410,572, filed September 13, 2002." However the Preliminary filed on January 30, 2008, to correct the PCT application number states "This application is a 371 of PCT/US2003/028622 filed, September 11, 2003, which claims benefit of U.S. Provisional Application Serial No. 60/410,572, filed September 13, 2002, both of which are incorporated herein by reference in their entirety for all purposes." The phrase "both of which are incorporated herein by reference in their entirety for all purposes" is new matter as it was not part of the originally filed disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Response to Arguments***

In the reply dated November 3, 2008, applicants argue that an amendment introducing or modifying a priority claim is not new matter. The objection under 35 U.S.C. 132(a) is not directed to modifying or correcting the priority claim, but instead the

objection is directed to the phrase "both of which are incorporated herein by reference in their entirety for all purposes." This phrase constitutes new matter as it was not part of the originally filed disclosure.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 25 remains rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The antibodies of claim 25 include the naturally occurring antibodies to the virus capsid proteins. Even though the virus is non-naturally occurring (e.g., capsid from virus A and in the context of virus B), it does not mean that a natural antibody to the capsid protein of virus A would not bind to the capsid protein A in the context of the non-naturally occurring virus. It is possible that the non-natural aspect of the virus occurs in a non-capsid protein (e.g., envelope or another structural or non-structural protein) that would not affect the naturally-occurring antibody binding to the viral capsid protein. Amending the claim to recite "An isolated antibody" would overcome this rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al. (Journal of General Virology, 1994, 75:895-900).

The claims are directed to antibodies to viral capsids of a non-naturally occurring virus.

McGuire et al. discloses infected cells with recombinant vaccinia viruses expressing the equine infectious anaemia virus (EIAV) gag gene (VGag) or gag plus the 5' pol encoding protease (VGag/PR). The cells were evaluated with monoclonal antibody to a p26 capsid protein linear epitope (QEISKFLTD) (see, for example, the abstract and page 896, left column).

The recombinant vaccinia virus of McGuire et al. is non-naturally occurring and the monoclonal antibody is directed to the p26 capsid protein.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (Virology, 1996, 217:252-261).

The claims are directed to antibodies to viral capsids of a non-naturally occurring virus.

Hardy et al. discloses infecting insect cells with recombinant baculovirus expressing Norwalk virus (NV) capsid protein. Hardy et al. also discloses monoclonal antibodies that recognize the rNV capsid proteins expressed in the infected insect cells (see, for example, the abstract and page 252, right column).

The recombinant baculovirus of Hardy et al. is non-naturally occurring and the monoclonal antibody is directed to the capsid protein of the recombinant virus.

### ***Response to Arguments***

In the reply dated November 3, 2008, applicants argue that the antibodies disclosed in the above-cited references were obtained/prepared from a process that is different from that which is claimed by applicants. This argument has been fully considered, but not found to be persuasive.

Claims 25 and 26 are product-by-process claims, which are drawn to an antibody specific to the viral capsid of a non-naturally occurring virus. The method steps recited to produce the antibody are not considered when determining patentability of the product (MPEP § 2113). In *In re Thorpe*, the court stated, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/  
Examiner, Art Unit 1648

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

<b>Application Number</b> 	Application/Control No.	Applicant(s)/Patent under Reexamination
	10/527,973	LINGAPPA ET AL.
Examiner	Art Unit	
NICOLE KINSEY WHITE	1648	